**Local Supplement to Sponsor Protocol (HRP-508)**

**INSTRUCTIONS:**

* Only use this form when also providing a protocol (not just a grant application) from a sponsor or lead site (e.g. commercial, NIH, etc.). For all other protocols use HRP-503.
* Depending on the nature of your study, some sections may not be applicable to your research. If so, you must provide the reason why the section is not applicable. For example, when accurate, the statement, “local inclusion criteria will not differ from those of the sponsor’s protocol” could be provided in response to question 1.1.
* Provide the entire Sponsor protocol as a separate upload in Click IRB.
* Unless otherwise specified, provide only site-specific information below.
* When you write a single site supplement, keep an electronic copy. You will need to modify this copy when making changes. When you make changes, use the Track Changes feature.
* Do not remove the italics instructions or headings.
* If you are pasting information from other documents be sure to use the "Merge Formatting" paste option so that the formatting of the response boxes is not lost. If information is presented outside of the response boxes, it may not be accepted.
* If this study involves multiple participant groups who participate in different research procedures, consent processes, etc., be certain to provide information in each applicable section for each participant group and clearly label each participant group within a section or subsection.

**PROTOCOL TITLE:**

*Include the full protocol title.*

Response:

**PRINCIPAL INVESTIGATOR:**

*Name*

*Department*

*Telephone Number*

*Email Address*

Response:

**FUNDING:**

*Indicate any funding for this proposal. This should match the Funding Sources page in Click IRB.*

Response:

**GRANT APPLICABILITY:**

*Describe whether or not this protocol is funded by a grant or contract and if so, what portions of the grant this study covers.*

Response:

**VERSION NUMBER/DATE:**

*Include the version number and date of this site supplement.*

Response:

**Revision History**

|  |  |  |  |
| --- | --- | --- | --- |
| **Revision #** | **Version Date** | **Summary of Changes** | **Consent Change?** |
|  |  |  |  |
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# 

# Study Summary

|  |  |
| --- | --- |
| **Study Title** |  |
| **Study Design** |  |
| **Primary Objective** |  |
| **Secondary Objective(s)** |  |
| **Research Intervention(s)/ Investigational Agent(s)** |  |
| **IND/IDE #** |  |
| **Study Population** |  |
| **Sample Size** |  |
| **Study Duration for individual participants** |  |
| **Study Specific Abbreviations/ Definitions** |  |

# Study Intervention/Investigational Agent

* 1. If the research involves drugs or device, describe your plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and be used only by authorized investigators.
     + If the control of the drugs or devices used in this protocol will be accomplished by following an established, approved organizational SOP (e.g., Research Pharmacy SOP for the Control of Investigational Drugs, etc.), please reference that SOP in this section.

Response:

* 1. If the drug is investigational (has an IND) or the device has an IDE or a claim of abbreviated IDE (non-significant risk device), include the following information:
     + Identify the holder of the IND/IDE/Abbreviated IDE.
     + Explain procedures followed to comply with sponsor requirements for FDA regulated research for the following:

|  |  |  |  |
| --- | --- | --- | --- |
|  | ***Applicable to:*** | | |
| ***FDA Regulation*** | ***IND Studies*** | ***IDE studies*** | ***Abbreviated IDE studies*** |
| ***21 CFR 11*** | ***X*** | ***X*** |  |
| ***21 CFR 54*** | ***X*** | ***X*** |  |
| ***21 CFR 210*** | ***X*** |  |  |
| ***21 CFR 211*** | ***X*** |  |  |
| ***21 CFR 312*** | ***X*** |  |  |
| ***21 CFR 812*** |  | ***X*** | ***X*** |
| ***21 CFR 820*** |  | ***X*** |  |

Response:

# Inclusion and Exclusion Criteria\*

* 1. Describe any inclusion or exclusion criteria that will differ for your local site compared to the sponsor’s protocol. For example, if the sponsor’s protocol allows the enrollment of children but your site will not enroll children, indicate that here.

Response:

# Withdrawal of Subjects\*

* 1. Describe procedures that will be followed locally, if different than the sponsor’s protocol, when subjects withdraw from the research.

Response:

# Vulnerable Populations\*

* 1. If the research involves individuals who are vulnerable to coercion or undue influence, describe additional safeguards included to protect their rights and welfare.
     + If the research involves pregnant women, review “CHECKLIST: Pregnant Women (HRP-412)” to ensure that you have provided sufficient information.
     + If the research involves neonates of uncertain viability or non-viable neonates, review “CHECKLIST: Neonates (HRP-413)” or “HRP-414 – CHECKLIST: Neonates of Uncertain Viability (HRP-414)” to ensure that you have provided sufficient information.
     + If the research involves prisoners, review “CHECKLIST: Prisoners (HRP-415)” to ensure that you have provided sufficient information.
     + If the research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research (“children”), review the “CHECKLIST: Children (HRP-416)” to ensure that you have provided sufficient information.
     + If the research involves cognitively impaired adults, review “CHECKLIST: Cognitively Impaired Adults (HRP-417)” to ensure that you have provided sufficient information.
     + Consider if other specifically targeted populations such as students, employees of a specific firm or educationally/economically disadvantaged persons are vulnerable to coercion or undue influence. The checklists listed above for other populations should be used as a guide to ensure that you have provided sufficient information.

Response:

# Sharing of Results with Subjects\*

* 1. Describe whether or not results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject’s primary care physicians) and if so, describe how it will be shared.

Response:

# Setting

* 1. Describe the local sites or locations where your research team will conduct the research.

Response:

* 1. Identify where your research team will identify and recruit potential subjects.

Response:

* 1. Identify where research procedures will be performed.

Response:

* 1. Describe the composition and involvement of any community advisory board.

Response:

* 1. For research conducted outside of the organization and its affiliates describe:
* Site-specific regulations or customs affecting the research for research outside the organization.
* Local scientific and ethical review structure outside the organization.

Response:

# Resources Available

* 1. Describe the qualifications (e.g., training, experience, oversight) of you and your staff as required to perform their role. When applicable describe their knowledge of the local study sites, culture, and society. Provide enough information to convince the IRB that you have qualified staff for the proposed research. If you specify a person by name, a change to that person will require prior approval by the IRB. If you specify people by role (e.g., coordinator, research assistant, co-investigator, or pharmacist), a change to that person will not typically require prior approval by the IRB, provided that person meets the qualifications described to fulfill their roles.

Response:

Describe other resources available to conduct the research: For example, as appropriate:

* 1. Justify the feasibility of recruiting the required number of suitable subjects within the agreed recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?

Response:

* 1. Describe the time that you will devote to conducting and completing the research.

Response:

* 1. Describe your facilities.

Response:

* 1. Describe the availability of medical or psychological resources that subjects might need as a result of an anticipated consequences of the human research.

Response:

* 1. Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.

Response:

# Prior Approvals

* 1. Describe any approvals that will be obtained prior to commencing the research. (E.g., school, external site. funding agency, laboratory, radiation safety, or biosafety approval.)

Response:

# Local Recruitment Methods

*This section is for recruitment methods under the control of the local site and not central recruitment managed by the sponsor.*

* 1. Describe when, where, and how potential subjects will be recruited.

Response:

* 1. Describe the source of subjects.

Response:

* 1. Describe the methods that will be used to identify potential subjects.

Response:

* 1. Describe materials that will be used to recruit subjects. (Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.)

Response:

* 1. Describe the amount and timing of any payments to subjects.

Response:

# Local Number of Subjects

* 1. Indicate the total number of subjects to be accrued locally.

Response:

* 1. If applicable, distinguish between the number of subjects who are expected to be enrolled and screened, and the number of subjects needed to complete the research procedures (i.e., numbers of subjects excluding screen failures.)

Response:

# Data Management and Confidentiality

Describe the local procedures for maintenance of confidentiality.

* 1. Where and how data or specimens will be stored locally?

Response:

* 1. How long the data or specimens will be stored locally?

Response:

* 1. Who will have access to the data or specimens locally?

Response:

* 1. Who is responsible for receipt or transmission of the data or specimens locally?

Response:

* 1. How data and specimens will be transported locally?

Response:

# Provisions to Protect the Privacy Interests of Subjects

* 1. Describe the steps that will be taken to protect subjects’ privacy interests. “Privacy interest” refers to a person’s desire to place limits on whom they interact or whom they provide personal information.

Response:

* 1. Describe what steps you will take to make the subjects feel at ease with the research situation in terms of the questions being asked and the procedures being performed. “At ease” does not refer to physical discomfort, but the sense of intrusiveness a subject might experience in response to questions, examinations, and procedures.

Response:

* 1. Indicate how the research team is permitted to access any sources of information about the subjects.

Response:

# Compensation for Research-Related Injury

* 1. If the research involves more than Minimal Risk to subjects, describe the available compensation in the event of research related injury.

Response:

* 1. Provide a copy of contract language, if any, relevant to compensation for research-related injury.

Response:

# Economic Burden to Subjects

* 1. Describe any costs that subjects may be responsible for because of participation in the research, e.g., fuel, parking, childcare.

Response:

# Consent Process

* 1. Indicate whether you will be obtaining consent.

Response:

* 1. Describe where the consent process take place.

Response:

* 1. Describe any waiting period available between informing the prospective subject and obtaining the consent.

Response:

* 1. Describe any process to ensure ongoing consent.

Response:

* 1. Describe whether you will be following “SOP: Informed Consent Process for Research (HRP-090).” Pay particular attention to Sections 5.4-5.9. If not, or if there are any exceptions or additional details to what is covered in the SOP, describe:
     + The role of the individuals listed in the application as being involved in the consent process.
     + The time that will be devoted to the consent discussion.
     + Steps that will be taken to minimize the possibility of coercion or undue influence.
     + Steps that will be taken to ensure the subjects’ understanding.

Response:

**Non-English Speaking Subjects**

* 1. Indicate what language(s) other than English are likely to be spoken/understood by your prospective study population or their legally authorized representatives.

Response:

* 1. Indicate whether you will include non-English speaking individuals in your study. **Provide justification if you will exclude non-English speaking individuals.**

In order to meet one of the primary ethical principles of equitable selection of subjects, non-English speaking individuals may **not** be routinely excluded from research as a matter of convenience.

In cases where the research is of therapeutic intent or is designed to investigate areas that would necessarily require certain populations who may not speak English, the researcher is required to make efforts to recruit and include non-English speaking individuals. However, there are studies in which it would be reasonable to limit subjects to those who speak English. Some examples include pilot studies, small unfunded studies with validated instruments not available in other languages, studies with numerous questionnaires, and some non-therapeutic studies which offer no direct benefit.

Response:

* 1. If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language, how you will ensure that subjects are provided with a sufficient period of time to consider taking part in the research study, and any process to ensure ongoing consent. Indicate the language that will be used by those obtaining consent.

NOTE: Guidance is provided on “SOP: Informed Consent Process for Research (HRP-090).”

Response:

**Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception)**

* 1. Review the “CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)” to ensure you have provided sufficient information for the IRB to make these determinations. Provide any additional information necessary here:

Response:

* 1. If the research involves a waiver the consent process for planned emergency research, please review the “CHECKLIST: Waiver of Consent for Emergency Research (HRP-419)” to ensure you have provided sufficient information for the IRB to make these determinations. Provide any additional information necessary here:

Response:

**Subjects who are not yet adults (infants, children, teenagers)**

* 1. Describe the criteria that will be used to determine whether a prospective subject has not attained the legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted. (E.g., individuals under the age of 18 years.) For research conducted in NY state, review “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)” to be aware of which individuals in the state meet the definition of “children.”

Response:

* 1. For research conducted outside of NY state, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of “children” in “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013).”

Response:

* 1. Describe whether parental permission will be obtained from:
     + Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
     + One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.

Response:

* 1. Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine these individuals’ authority to consent to each child’s general medical care.

Response:

* 1. Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent.

Response:

* 1. When assent of children is obtained describe whether and how it will be documented.

Response:

**Cognitively Impaired Adults**

* 1. Describe the process to determine whether an individual is capable of consent. The IRB sometimes allows the person obtaining assent to document assent on the consent document and does not automatically require assent documents to be used.

Response:

**Adults Unable to Consent**

When a person is not capable of consent due to cognitive impairment or decisional incapacity, a legally authorized representative must be used to provide consent and, where possible, assent of the individual should also be solicited.

* 1. List the individuals from whom permission will be obtained in order of priority. (e.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child.) For research conducted in NY state, review “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)” to be aware of which individuals in the state meet the definition of “legally authorized representative.” The list in the consent template signature section corresponds to the priority list for New York State.

Response:

* 1. For research conducted outside of New York state, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in this research. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of “legally authorized representative” in “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013).”

Response:

* 1. Describe the process for assent of the subjects. Indicate whether:
     + Assent will be required of all, some, or none of the subjects. **If some, indicate which subjects will be required to assent and which will not.**
     + **If assent will not be obtained from some or all subjects, an explanation of why not.**
     + Describe whether assent of the subjects will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require subjects to sign assent documents.

Response:

# Process to Document Consent in Writing

* 1. Describe whether you will be following “SOP: Written Documentation of Consent (HRP-091).” If not, describe whether and how consent of the subject will be obtained including whether or not it will be documented in writing.

Response:

# Data and Specimen Banking\*

* 1. The sponsor’s protocol may require banking data or specimens for future use and both storage and use will be determined by the sponsor. If additional data or specimens will be banked locally for future use, describe where the specimens will be stored, how long they will be stored, how the specimens will be accessed, and who will have access to the specimens.

Response:

* 1. List the data to be stored or associated with each specimen banked locally.

Response:

* 1. Describe the procedures to release locally banked data or specimens, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.

Response: